

Langstaff Plaintiffs to compensate Drs. Lesko and Mitchell if any of their testimony is taken.

Schering Corp. v. Amgen, Inc., 1998 WL 552944 (D.Del); Wright v. Jeep Corp., 547 F. Supp. 871 (E.D. Mich. 1982).

II. THE SUBPOENA DUCES TECUM SHOULD BE QUASHED BECAUSE IT IS SUBSTANTIALLY BURDENSOME AND SEEKS IRRELEVANT AND CONFIDENTIAL INFORMATION.

The deposition subpoenas issued by Langstaff Plaintiffs require Drs. Mitchell and Lesko to produce documents that are identical to documents listed in an earlier subpoenas duces tecum that were served upon the custodian of records for Slone and Allen Mitchell in November of 2003. See Exhibits 4 and 5. Slone and Dr. Mitchell have already served upon the attorney for Langstaff Plaintiffs written objections to the inspection or copying of the designated materials. Exhibit 6. As such, under Fed. R. Civ. P. 45(c)(2)(B), Langstaff Plaintiffs are not entitled to the documents except pursuant to an order of this Court.

Even if this Court allows Drs. Mitchell and Lesko to be deposed, it should not require them to comply with the lengthy document requests that accompany their deposition subpoenas. Objections to specific requests are as follows:

**Request No. 3:**

All summaries of data showing the total number of skin-related adverse reactions or other ADEs in the Boston Fever Study and any other clinical trial involving ibuprofen and children, including, but not limited to the following ADEs: angioedema, epidermal necrolysis, erythema multiforme, erythema nodosum, exfoliative dermatitis, photosensitivity, pustular rash, skin necrosis, Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) or Lyell's syndrome, death, vesicular rash, bullous rash, fixed drug eruption, lupus rash, macular papular rash, petechial rash, pruritus, purpura, rash, skin disorder, stomatitis, allergic reaction and urticaria.

**Response to Request No. 3:**

Plaintiffs object to this request as overbroad because of the volume of documents requested and because it appears to ask for information on all skin related adverse drug events

(ADEs) in the Boston University Fever Study and does not limit the request to Stevens Johnson Syndrome (“SJS”) or toxic epidermal necrolysis (“TEN”), the specific injuries allegedly suffered by Langstaff Plaintiffs as a result of Kaitlyn Langstaff’s ingestion of Children’s Motrin. Further, Langstaff Plaintiffs have asked for identical information from McNeil in Request No. 8 of their Request for Production of Documents propounded on McNeil. Exhibit 7. Based on similar objections by McNeil, the District Court in California ruled as follows:

With respect to Document Request Nos. 5-9, 12 and 13, plaintiffs seek production of (a) Case Report Forms (pre-marketing) and (b) source documents (post-marketing) for adverse drug event (“ADE”) reports. Here again, the parties’ dispute appears to center upon whether McNeil should be compelled to produce all information, regardless of whether it might pertain to SJS/TEN or EM.

No later than **April 12, 2004**, and to the extent a particular request calls for such data, McNeil shall produce (a) Case Report Forms for clinical trials data that identifies, describes, refers, relates or pertains to SJS/TEN or EM; and (b) underlying documentation for ADE reports that refers, relates or pertains to SJS/TEN or EM. To the extent ADE records exist in electronic form, at the hearing plaintiffs’ counsel agreed that plaintiffs will accept electronic files in lieu of paper documentation.

Exhibit 8: Order Granting in Part and Denying in Part Plaintiffs’ Second Amended Motion to Compel Discovery. Entered by U.S. Magistrate Judge Howard R. Lloyd on March 29, 2004 (“Magistrate’s Order”).

McNeil has produced the requested records relating to adverse reactions recorded during the Boston University Fever Study. In fact, Langstaff Plaintiffs have received over 70 boxes of documents relating to the Boston University Fever Study, comprising 97,000 pages of documents. Exhibit 9: Declaration of Kenneth P. Conour in Opposition to Plaintiffs’ Second Amended Motion to Compel, pp. 9-10, ¶¶ 25-27 (“Conour Dec.”). Requiring Drs. Mitchell and Lesko to produce voluminous documents that have already been produced by McNeil is unnecessary and unduly burdensome.

**Request No. 4:**

All presentations, slides, lectures or related documents that were presented to the FDA on behalf of McNeil Consumer Healthcare regarding ibuprofen.

**Response to Request No. 4:**

Again, McNeil has already provided Langstaff Plaintiffs with a copy of their complete submission to the FDA when seeking the over-the-counter approval of Children's Motrin. See Exhibit 7: Requests Nos. 10, 11; Exhibit 9: Conour Dec. p. 2, ¶¶ 2-5. Conour states that McNeil has produced "defendants' complete data from the Boston University Fever Study, which involved more than 80,000 patients. That data includes both safety and efficacy information collected during the 2½ year trial. Defendants have also produced all electronic files located in the NDAs requested by plaintiffs." As these documents have been produced by McNeil, there is no reason to require Drs. Mitchell and Lesko to provide these documents again. Plaintiffs further object to this request as unreasonable, unnecessary, and unduly burdensome because of the volume of documents requested.

**Request No. 5:**

All documents showing your clinical trial policies and procedures for conducting the Boston Fever Study.

**Response to Request No. 5:**

To the best of Plaintiff's knowledge, the protocol for the Boston University Fever Study is set forth in the New Drug Application documents that McNeil submitted to the FDA and that McNeil has produced to Langstaff Plaintiffs as set forth in Mr. Conour's declaration. See Exhibit 9: Conour Dec. p. 2, ¶¶ 2-5. It is unduly burdensome, duplicative and unnecessary to require Drs. Lesko and Mitchell to produce such materials.

**Request No. 6:**

All warnings, instructions, labels or package inserts used for ibuprofen in the Boston Fever Study.

**Response to Request No. 6:**

Plaintiffs object to this request on the grounds that it is irrelevant. The adverse event reportedly experienced by Kaitlyn Langstaff occurred in 2002. The Boston University Fever Study was conducted by SEC in 1991-1993, and the “warnings, instructions, labels or package inserts” used for ibuprofen in that study are not relevant to Kaitlyn Langstaff’s alleged injuries. Further, to the best of SEC’s knowledge, the information requested can be found in the NDA documents that McNeil has already produced. See Exhibit 9: Conour Dec. p. 2, ¶¶ 2-5. It is unduly burdensome, duplicative and unnecessary to require the SEC to produce such materials.

**Request No. 7:**

Copies of all research studies, including drafts of or final manuscripts sponsored by McNeil Consumer Healthcare, whether published in peer-reviewed journals or unpublished studies, on the subjects of adverse skin reactions by adults or children from ibuprofen; SJS or TEN caused by or associated with ibuprofen; renal toxicity of ibuprofen; gender differences of adverse reactions to ibuprofen.

**Response to Request No. 7:**

Plaintiffs object to this request because Langstaff Plaintiffs have readily available access to the published articles resulting from the Boston University Fever Study and to the referenced works therein. Langstaff Plaintiffs have made no showing as to why they need drafts of such manuscripts. With regard to research studies not associated with the Boston University Fever Study, Langstaff Plaintiffs also have access to all research manuscripts in the public domain. To the extent they seek other reports or studies, the request contravenes Rule 45(c)(3)(B) by seeking disclosure of unpublished reports that represent an unretained expert’s opinion.

**Request No. 8:**

All drug safety committee, data and monitoring committee or other committee reports in the Boston Fever Study that reviewed the safety of ibuprofen that discuss any adverse event or reaction associated with ibuprofen, including but not limited to: skin conditions, such as rash, erythema multiforme, SJS, TEN, or renal failure.

**Response to Request No. 8:**

Plaintiffs object to this request as unreasonable, unnecessary, and unduly burdensome because it requests committee reports regarding “any adverse event or reaction associated with ibuprofen” and is not confined to SJS or TEN, the specific injuries allegedly suffered by Langstaff Plaintiffs as a result of Kaitlyn Langstaff’s ingestion of pediatric Motrin. The documents requested bear only slight relevance to the subject matter of the litigation, and the resources necessary to obtain the information requested is highly disproportionate to the relevance of the information.

**Request No. 9:**

All contracts or agreements for the employment of Boston University or Boston University Medical Center or Slone Epidemiology Unit, School of Public Health, Boston University School of Medicine to conduct the clinical trial that was known as the Boston Fever Study, including all correspondence, contracts, memorandums, agreements, payments, reports or other documents that dealt with the Boston Fever Study.

**Response to Request No. 9:**

Plaintiffs object to this request on the grounds that it is irrelevant, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence and is duplicative of an identical discovery request propounded upon McNeil by Langstaff Plaintiffs. See Exhibit 7, Request no. 33. Langstaff Plaintiffs can make no showing that the contracts, communications, and business dealings between Drs. Mitchell, Lesko and McNeil or between Slone and McNeil have any relevance to this lawsuit, and Langstaff Plaintiffs have no reasonable basis for seeking such documents other than to harass these physicians or to obtain confidential research, development or commercial information in violation of Rule 45(c)(3)(B). At a minimum, before Plaintiffs are required to produce any information, this court should require Langstaff Plaintiffs to have in place an appropriate protective order that will assure the confidentiality of such information.

**Request No. 10:**

Any and all documents pertaining to Institutional Review Board for Human Research at Boston University Medical Center's approval, monitoring or supervision of the Boston Fever Study, including but not limited to: safety and efficacy analyses of ibuprofen by the Advisory Committee or the Data Monitoring Committee of the Institutional Review Board for Human Research at Boston University Medical Center.

**Response to Request No. 10:**

This request is irrelevant, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence. Langstaff Plaintiffs can make no showing that documents relating to the Institutional Review Board's approval of the Boston University Fever Study in the early 1990s have any relevance to injuries suffered by Kaitlyn Langstaff in 2002. Further, there is no Advisory Committee or Data Monitoring Committee of the Institutional Review Board. The Boston University Fever Study Advisory Committee was a separate committee that provided independent guidance to Slone Epidemiology Center and served as the data monitoring committee.

**Request No. 11:**

Any and all agreements, contracts, consulting agreements, proof of payments, 1099 forms, checks, reports, memorandums between Samuel Lesko, M.D. or Allen A. Mitchell, M.D., or Slone Epidemiology Unit, School of Public Health, Boston University School of Medicine and McNeil Consumer Healthcare or Johnson & Johnson.

**Response to Request No. 11:**

Drs. Mitchell and Lesko have not been retained as experts for McNeil. As such, they are not required, pursuant to Rule 26(a)(2)(B) to disclose "compensation to be paid for the study and testimony." The financial information sought by Langstaff Plaintiffs is confidential, and they can make no showing that the general contracts, communications, and business dealings between Drs. Mitchell and Lesko and McNeil have any relevance to this lawsuit. Langstaff Plaintiffs have no reasonable basis for seeking such documents other than to harass Drs. Mitchell and Lesko or to obtain confidential financial, research, development or commercial information in

violation of Rule 45(c)(3)(B). Further, the request is not limited to compensation received by Drs. Lesko, Mitchell or Slone in connection with the Boston University Fever Study, but instead encompasses all agreements and financial arrangements between Drs. Mitchell, Lesko, Slone and McNeil without any limitation as to time period or subject of the arrangement. Langstaff Plaintiffs should not be allowed to go on this fishing expedition without making a strong showing of relevance sufficient to outweigh the substantial intrusion on the personal privacy of Drs. Mitchell and Lesko and intrusion into confidential business arrangements of Boston University.

**Request No. 12:**

Any and all study protocols or drafts of study protocols for the Boston Fever Study.

**Response to Request No. 12:**

To the best of Dr. Mitchell and Lesko's knowledge, the protocol for the Boston University Fever Study is set forth in the New Drug Application documents that McNeil submitted to the FDA and that McNeil has produced to Langstaff Plaintiffs. See Exhibit 9: Conour Dec. p. 2, ¶¶ 2-5. It is unduly burdensome, duplicative and unnecessary to require Drs. Lesko and Mitchell to produce such materials. Further, Langstaff Plaintiffs can make no showing that "drafts" of study protocols have any relevance to their lawsuit.

**Request No. 13:**

Any and all documents submitted to the U.S. FDA Center for Drug Evaluation and Research, Non-Prescription Drug Advisory Committee from 1992 to the present regarding Children's Motrin or ibuprofen by Dr. Samuel Lesko, Dr. Allen Mitchell or any staff member for the Slone Epidemiology Unit.

**Response to Request No. 13:**

McNeil has provided Langstaff Plaintiffs with the NDA for Children's Motrin. See Exhibit 9: Conour Dec. p. 2, ¶¶ 2-5. To the best of their knowledge, Drs. Mitchell and Lesko are not aware of any documents that were submitted directly by them or by Slone to the FDA in

connection with the Boston University Fever Study, as they believe that all such documents were submitted by McNeil.

**Request No. 14:**

A list of all 1700 physicians who participated in the Boston Fever Study along with their addresses and phone numbers.

**Response to Request No. 14:**

Plaintiffs strongly object to this request on the grounds that it is irrelevant, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence. Langstaff Plaintiffs can have no conceivable basis for requesting the contact information for the doctors participating in the study. Plaintiffs further strongly object to this request to the extent that Langstaff Plaintiffs wish to secure this information in order to contact the physicians who engaged in the Study. Many of these doctors are currently participating in ongoing studies conducted by Slone for various federal agencies. The physicians' cooperation in such research studies will be chilled or curtailed if, as a consequence of participation, physicians are contacted by plaintiffs' attorneys seeking to verify information obtained from researchers. Such physicians might also knowingly or unknowingly provide information that would allow Langstaff Plaintiffs to identify particular patients.

**Request No. 15:**

Any and all printouts of every e-mail between Samuel Lesko, M.D. or Allen Mitchell, M.D. or the Slone Epidemiology Unit of Boston University and McNeil Consumer Healthcare or their agents, employees or designated representatives concerning the evaluation of the safety and efficacy of ibuprofen in children.

**Response to Request No. 15:**

Plaintiffs object to this request on the grounds that it is irrelevant, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence. Langstaff Plaintiffs cannot demonstrate that e-mails between Drs. Lesko and Mitchell and McNeil or Slone employees and McNeil have any relevance to their claims. Again, Langstaff Plaintiffs should



not be allowed to go on this fishing expedition without making a strong showing of relevance sufficient to outweigh the substantial intrusion on the personal privacy of Drs. Mitchell and Lesko and the intrusion into confidential business arrangements of Boston University.

**Request No. 16:**

Any and all documents that detail the financial support, grants, donations, or money paid to the Slone Epidemiology Unit of Boston University given by McNeil Consumer Healthcare for the last 3 years.

**Response to Request No. 16:**

Plaintiffs object to this request on the grounds that it is irrelevant, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence. The Boston University Fever Study was conducted from 1991 to 1993. Langstaff Plaintiffs can make no showing that financial transactions of Slone with McNeil over the last three years have any relevance to this lawsuit, and Langstaff Plaintiffs have no reasonable basis for seeking such documents other than to harass Drs. Mitchell or Lesko or to obtain confidential financial research, development or commercial information in violation of Rule 45(c)(3)(B).

**Request No. 17:**

Any and all documents that detail the meetings and discussions between McNeil Consumer Healthcare and Dr. Samuel Lesko and Dr. Allen Mitchell, or any staff member, of Boston University regarding the New Drug Application 20-516, 20-601, 20-602 and 20-603 also known as Children's Motrin.

**Response to Request No. 17:**

Plaintiffs object to this request on the grounds that it is irrelevant, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence. Langstaff Plaintiffs cannot demonstrate that meetings between Drs. Lesko and Mitchell or Slone and McNeil have any relevance to their claims. Again, Langstaff Plaintiffs should not be allowed to go on this fishing expedition without making a strong showing of relevance sufficient to outweigh the

substantial intrusion on the personal privacy of Drs. Mitchell and Lesko and the intrusion into confidential business arrangements of Boston University.

**Request No. 18**

All expert reports generated by Dr. Samuel Lesko, Dr. Allen Mitchell or any staff member of Boston University for McNeil Consumer Healthcare regarding ibuprofen.

**Response to Request No. 18:**

Neither Dr. Mitchell nor Dr. Lesko has been retained as an expert by McNeil. As such, Langstaff Plaintiffs have no right, under Fed. R. Civ. P. 26(a)(2)(B) to any expert reports. Notwithstanding this objection, Drs. Lesko and Mitchell have not produced any expert reports other than published studies of their research, which are in the public domain, or materials provided to McNeil for submission to the FDA, which Langstaff Plaintiffs have already obtained from McNeil.

**Request No. 19:**

All minutes of meetings, or reports or unpublished documents from any scientific or medical advisory committee participating in the Boston Fever Study.

**Response to Request No. 19:**

Plaintiffs object to this request as unreasonable, unnecessary, and unduly burdensome. Langstaff Plaintiffs have made no showing that there is any evidence relevant to their lawsuit that is contained within minutes of meetings of the Boston University Fever Study Advisory Committee. Absent such a showing, Langstaff Plaintiffs should not be required to produce voluminous documents, which would create a substantial burden and undue hardship upon the Plaintiffs.

### CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that this Court exercise its discretion to quash to deposition subpoenas as well as the subpoenas duces tecum issued by Langstaff Plaintiffs to Drs. Allen Mitchell and Samuel Lesko.

Respectfully submitted,

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TRUSTEES OF BOSTON UNIVERSITY,  
By their attorney,

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### CERTIFICATE OF SERVICE

I hereby certify that on this day a true copy of the above document was served upon the attorney of record for each other party by mail ~~by hand~~.

Date: April 28, 2004 Erik Geetter